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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/642,236

08/17/2000

George R. Schwartz

41145-1001

6972

7590

05/20/2002

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EXAMINER

KAM, CHIH MIN

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 05/20/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/642,236

Applicant(s)

SCHWARTZ, GEORGE R.

Examiner

Chih-Min Kam

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-60 is/are pending in the application.
- 4a) Of the above claim(s) 23-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-59 is/are rejected.
- 7) ☒ Claim(s) 60 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Continued Prosecution Application

1. The request (Paper No. 11) filed on March 12, 2002 for a Continued Prosecution Application (CPA) under 37 C.F. R. 1.53 (d) based on parent application No. 09/642,236 is acceptable and CPA has been established. An action on the CPA follows.

Status of the Claims

2. Claims 23-60 are pending.

Applicants' amendment filed on March 12, 2002 (Paper No. 12) is acknowledged. Applicants' response has been fully considered. Claims 1-22 have been cancelled, claims 23-32 are non-elected claims and stand withdrawn from consideration. New claims 33-60 have been added. Thus, claims 33-60 are examined.

Rejection Withdrawn

Claim Rejections - 35 USC § 112

3. The previous rejection of claims 1-22 under 35 USC § 112, first paragraph, is withdrawn in view of applicants' cancellation of the claim.

4. The previous rejection of claims 1-22 under 35 USC § 112, second paragraph, is withdrawn in view of applicants' cancellation of the claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1653

5. Claims 33-59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 33-59 are indefinite because of the use of the term “sufficient quantities of thrombopoietin” or “sufficient quantities of a thyroid regulatory agent”. The term “sufficient quantities of thrombopoietin” or “sufficient quantities of a thyroid regulatory agent” renders the claim indefinite, it is not clear what amount of thrombopoietin is used to induce endogenous production of platelet-derived growth factor in the mammal, or what amount of a thyroid regulatory agent is used to regulate cell division and oligodendroglia production.

6. Claims 33-44 are indefinite because they lack essential steps as claimed in the process of inducing regeneration and repair of nerve axon myelin coatings in a mammal with demyelination. The omitted step is a step whereby the outcome can be determined.

7. Claims 44 and 56 are indefinite because of the use of the term “at least ten days”. The term “at least ten days” renders the claim indefinite, it is not clear what are the maximal days for administering the thyroid regulatory agent subsequent to initial administration of the thrombopoietin.

8. Claim 60 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Art Unit: 1653

Conclusion

9. No claims are allowed.

Art of record

The following references appear to be related to the claimed invention. Thomas (U. S. Patent 5,879,673) teaches administration of thrombopoietin at single or multiple doses is used to increase the number of platelet for treating thrombocytopenia. Grinspan *et al.* (Annals of neurology 36, S140-S142 (supplement) 1994) teach platelet derived growth factor (PDGF) stimulates the formation of oligodendroglia from partially differentiated progenitor cells, and loss of oligodendroglia is frequently found in demyelinating diseases. Rodriguez-Pena (J. Neurobiol. 40, 497-512 (1997)) teaches thyroid hormone regulates the number of oligodendrocyte generated by directly promoting their differentiation. However, the references do not teach a method of inducing regeneration of nerve axon myelin coatings in a mammal with demyelination by administering thrombopoietin and a thyroid regulatory agent. Therefore, it appears the claimed invention is free of prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

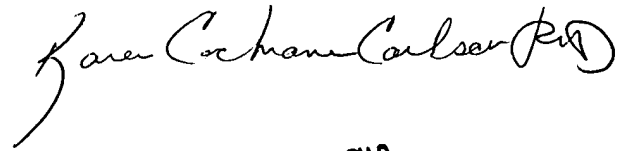
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Art Unit: 1653

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*
Patent Examiner

May 9, 2001

A handwritten signature in cursive script, reading "Karen Cochrane Carlson" followed by a circled "P" or "D".

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER